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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478
28596 7590 08/10/2011 GORE ENTERPRISE HOLDINGS, INC. 551 PAPER MILL ROAD P. O. BOX 9206 NEWARK, DE 19714-9206				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT 3738		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

08/499,423

Applicant(s)

CAMPBELL ET AL.

Examiner

BRIAN PELLEGRINO

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 9, 10, 20-23, 26 and 28-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 3-6, 9, 10, 20-23, 26 and 28-32 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/25/11 has been entered.

Response to Amendment

The declaration under 37 CFR 1.132 filed 5/25/11 is sufficient to overcome the rejection of claims 1,3-7,9,10,20,23,26,28-30 based upon 102 (e) over Myers (5628782).

Response to Arguments

Applicant's arguments, see page 8 of the response, filed 5/25/11, with respect to the rejection over Tu et al. (5061276) have been fully considered. However, after a careful further review of the MPEP, see section 2111.03, it must be noted that Applicants' modification to the claim to use the transitional phrase "consisting essentially of" does not necessarily define over the Tu reference because the phrase fails to exclude elements argued by Applicants not required by the claims. It must be noted that since the disclosure and claims fail to set forth any specifics as to the scope of "consisting

essentially of" it is not clear what would constitute a material change that could significantly affect the characteristics of the claimed liner. Thus, since Tu discloses that the PTFE outer film can be a blend having 95% PTFE, this clearly can be considered within the scope of the phrase "consisting essentially of" PTFE. Applicant's specification does not set forth a specific percentage of PTFE required to be present in a material if it were to be a blend. Thus, it is not clear as to the amount of other material possible in a blend with PTFE to be excluded from the blend encompassed in "consisting essentially of" for the covering to be solely PTFE. Thus, it can be interpreted that a small percentage of another material is within the realm of the claim scope since Tu states that only 5% of an elastomer is present in a PTFE film blend, col. 12, lines 52-54, col. 14, lines 15-20. MPEP states the applicant has the burden of showing that the inclusion of additional components would materially change the characteristics of applicant's invention, i.e. grafts tested in the submitted declaration of 5/25/11 to show the Myers '782 grafts that possessed or comprised the same material as claimed were alleged to be generally the same as Myers grafts did not have the claimed property. It is noteworthy that Applicant fails to argue that the claims do not exclude other materials by using "consisting essentially of" in the argument against the Myers '782 reference despite it having fibers but only attempted to show that the prior art did not possess the claimed property of expansion of 100% in circumference with no arguments that the claims exclude these other elements. The prior art graft liner of Tu et al. has the same materials as claimed and functional capabilities as claimed as best can be determined and because the Patent & Trademark Office does not have the testing facilities to

provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93). In addition it also is noted that the claims fail to set forth any limits in pressures, thus it is difficult to assess what would be analogous pressures subjected to a similar prior art device for the function to occur.

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-6,9,10,20-23,26,28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the change or condition of the diameter as the circumference expands. Claim 1 states "the circumference of the porous ptfе tube increases in response to the internal pressure..." and thus it is not

evident that these two characteristics in comparison are essentially the same. Claims 3-6,9,10,20-23,26,28-32 are rejected for being dependent upon a rejected base claim.

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

A dependent claim shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers..

Claims 3-6,9,10,20-23,26,28-32 are rejected under 35 U.S.C. 112, fourth paragraph, as being improper dependent claims for failing to include all the limitations of the claim from which it depends. Claim 1, of which all the claims depend on, is directed to a "blood conduit liner" having basically a tube and film covering. However, each of the dependent claims recite further limitations to an "article of claim 1" of which is not clear if is positively claiming all the elements of claim 1. What article? The entire article or some of the article? Thus, claims 3-6,9,10,20-23,26,28-32 are improper for further defining a feature not specific to claim 1.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5,20,22,23,26,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (5061276). Tu et al. disclose (col. 12, lines 20,21) a tube with an outer covering, Fig. 2. Tu also discloses the device can be used as a graft, col. 4, lines 53-55. Tu additionally discloses the tube is porous, col. 3, lines 4-6. Tu discloses the graft tube is made of polytetrafluoroethylene and has a covering of "consisting

essentially" polytetrafluoroethylene, col. 3, lines 45,46, abstract. Please note that the Examiner interprets the clause (per MPEP 2111.03) "consisting essentially of" as a comprising clause that does not exclude minimal amounts other materials. Therefore, it is understood that a large amount can be understood to be encompassed by using this transitional clause. Tu does disclose that when a blend of PTFE is used that the majority is 95% PTFE (col. 14, lines 15-20) and can thus be considered "essentially" PTFE. Tu et al. disclose the graft can be sutured to a conduit, col. 5, lines 55-63. Tu also discloses the graft circumference increases as a result of the blood pressure, col. 5, lines 46-48. Tu additionally discloses the tube can be expanded such that the second circumference (10mm) is at least 100% larger than the tube's original circumference (4mm) prior to the application of internal pressure, col. 10, lines 34-38. The polytetrafluoroethylene tube is disclosed as having a microstructure of nodes interconnected by fibrils, col. 7, lines 19-22. The circumference is fully capable of being increased by inflating a balloon. Tu also discloses the tube is placed on a tapered mandrel such that it forms a tapered end with a larger circumference at one end and a smaller second circumference at an opposing end, col. 10, lines 33-35. Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Regarding claim 27, it can be construed that an interior liner is present on the graft when multiple layers of PTFE are used, col. 3, lines 35-38.

Claims 1,3-6,9,10,20-23,26,28-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bowman (4283448). Bowman discloses (Fig. 1) a PTFE tube with a PTFE film disposed thereon, col. 2, lines 59-61. Bowman further disclose the tube and film are porous, Col. 4, lines 48,49,51,52. Since the claimed blood conduit liner is disclosed structurally as claimed by Bowman, the prior art device is capable of increasing its tube circumference 100% larger to a second circumference in response to an internal pressure and remain "substantially unchanged" at the second circumference. However, alternatively, it would have been obvious to one of ordinary skill in the art to have the blood conduit of Bowman capable of increasing in circumference, since it is well known that blood conduit liners have pressure flowing blood through them when in use and it would be advantageous to have these prosthetic conduits accommodate the varying blood flow pressures and eliminate failure or risk of burst under an increase in higher pressure. Regarding claims 3,4 Bowman disclose (col. 4, lines 2,3) the tube can have a wall thickness "*about*" 0.25mm or "*about*" 0.1mm. With respect to claim 5, Bowman disclose the tube has a microstructure of nodes interconnected by fibrils, col. 1, lines 66-68. Regarding claim 6, Bowman further disclose the porous ptfе film is helical, col. 2, lines 50-53. With respect to claim 9, the ptfе film is thermally bonded to the tube, col. 2, lines 54,55. Regarding claims 10,26 the use of "exhibits minimal recoil" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. The examiner asserts that the claimed physical property of the tube (in this case, having minimal recoil) is present in the prior art

material to some extent even though it is not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that this property is not present in the prior art article. Since the materials are the same as what is being claimed for blood conduit liner, it inherently possesses the same minimal recoil as the Applicant's claimed liner. With respect to claims 20-23,28-30 the device of Bowman is "adapted for use as an intraluminal graft". It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Bowman's ptfе tube is fully capable of being secured by sutures, or a stent and can be inflated by a balloon along with blood pressure capable of increasing its circumference. In addition it is capable of being used as a graft or as replacement vessel or applied to cover an anastomosis.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman '448 in view of Tu et al. '276. Bowman is explained supra. However, Bowman does not disclose a tube that is tapered with different diameters at its two ends. Tu et al. teach a tapered tube, see above. It would have been obvious to one of ordinary skill in the art to use a tapered tube conduit as taught by Tu et al. for the prosthesis of Bowman in a

vessel that it matches the contour in which it is placed in, such as going from a larger vessel to a smaller one.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman '448 in view of Hughes et al. (4728328). Bowman is explained supra. However, Bowman does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Bowman in a vessel such as the trachea requiring replacement to the two bronchi.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN PELLEGRINO whose telephone number is (571)272-4756. The examiner can normally be reached on M- F (9am-6:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738